

Remarks

Claims 1-6, 13-26, 56-61, 68-82, and 109-119 are pending in this application. Claims 7-12, 27-55, 62-67, and 83-108 were previously withdrawn from consideration as drawn to non-elected subject matter and have now been canceled for the same reason. Applicants reserve the right to file one or more continuing applications drawn to the subject matter of these canceled claims.

A Petition for a three-month extension of time and the associated fee are enclosed with this paper.

I. Response to Rejections under 35 U.S.C. § 103

A. Legal Standards under 35 U.S.C. § 103

The response to the previous Office Action included a review of the law of nonobviousness. That review is hereby incorporated by reference.

B. Factual and Legal Analysis

1. Claims Rejected over the Feldbrugge Reference

Claims 1-6, 13-16, 22-26, 56-61, 68-71, 77-82, 109-113, and 119 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 3,886,299 ("Feldbrugge").

Feldbrugge discloses dense, substantially unpuffed, fibrous products that simulate the muscle of animals or the flesh of

fish. (Abstr.) These fibrous products are made by "feeding a proteinaceous dough through a heated channel of decreasing volume to simultaneously elongate and thermally coagulate the dough and then releasing the compression without forcing the dough through a die while maintaining a pressure drop below 100 psi." (Abstr.) More particularly, Feldbrugge used a Sigma mixer to mix ingredients prior to extrusion in a single screw extruder. (Col. 7, lines 30-31; col. 7, line 67, through col. 8, line 2; col. 8, lines 14-17; col. 8, lines 55-56; col. 9, lines 2-4.) This process involved putting the dough in a heated chamber of decreasing volume. This extrusion process required compression and stretching for fiber formation. It also required the dough to show visible fibers during the mixing stage prior to extrusion. (Col. 5, lines 8-10 and 22-27.) Moreover, no exit die was used. (Abstr.; col. 2, lines 17-19; col. 3, lines 27-32; col. 7, lines 20-23.)

a. Feldbrugge Failed To Disclose Thermoplastic Extrusion

Applicants respectfully traverse the characterization of Feldbrugge's method as involving "thermoplastic extrusion." Applicants respectfully submit that the process described by Feldbrugge involved simple extrusion. The differences between thermoplastic extrusion and simple extrusion are widely recognized, as described in the following quotations:

(1) "Extrusion is simply the operation of shaping a plastic or dough-like material by forcing it through a restriction or die." M.N. Riaz, Introduction to extruders and their principles, in Extruders in Food Applications 1 (M.N. Riaz, ed., Technomic Publishing Co., Lancaster, PA, 2000).

(2) "Food extrusion has been practiced for over 50 years. Initially its role was limited to mixing and forming Now, the food extruder is considered a high-temperature, short-time bioreactor that transforms a variety of raw ingredients into modified intermediate and finished products." J.M. Harper, Food extruders and their application, in Extrusion Cooking 1 (Mercier, Linko & Harper, eds., American Assoc. Cereal Chemists, St. Paul, MN 1998).

(3) "Extrusion may be defined as forcing a pumpable product through a small opening to shape materials in a designated fashion. . . . A home cookie maker is a simple example of an extruder. . . . In many food extrusion processes, heating and cooking of raw materials occur as they are mixed and formed to produce essentially a finished product in a single operation." D.R. Heldman & R.W. Hartel, Food Extrusion, in Principles of Food Processing 253 (Chapman and Hall, New York 1997).

(4) "Thermoplastic extrusion is the process in which a low-water, powder-like raw material is pressed and heated simultaneously in a shear field, forced through a shaping die,

and rapidly hardened by cooling. . . . Three main steps of many food technologies, i.e., mixing of food system components, shaping of a food system and fixing the form and structure of a given food product, can be successively and continuously accomplished within the extruder barrel and at the exit." V.B. Tolstoguzov, Thermoplastic extrusion-the mechanism of the formation of extrudate structure and properties, 70 J. Assoc. Official Analytical Chemists 417, 419-420 (1993).

The last of these definitions distinguishes thermoplastic extrusion from simple extrusion. Feldbrugge describes simple extrusion, because (1) mixing was carried out in a mixer, not in the extruder; and (2) the mixture was not forced through an extrusion die.

Even though U.S. Patent No. 4,338,340 ("Morimoto") referred in 1982 to Feldbrugge as describing thermoplastic extrusion, Feldbrugge did not refer to its own process as thermoplastic extrusion, and the Feldbrugge process would not have been considered to be thermoplastic extrusion at the time the present application was filed due to a changed definition stemming from advances in the type of extruders in use.

b. Feldbrugge Failed To Disclose Each and Every Limitation of the Claimed Invention

Further, Feldbrugge did not disclose or suggest each and every limitation of the presently claimed invention. With

respect to claims 1 and 56, Feldbrugge did not disclose a thermoplastic extrusion product containing about 1-80% of food grade protein (or mixture of food grade proteins) and about 20-99% edible polysaccharide, where the food grade protein (or mixture of food grade proteins) comprises at least about 25% by weight of whey protein.

With respect to claims 2 and 57, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising about 15-65% by weight of food grade protein. Similarly, with respect to claims 3 and 58, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising about 16-48% by weight of food grade protein.

With respect to claims 4 and 59, Feldbrugge did not disclose or suggest a thermoplastic extrusion product further comprising up to about 75% by weight of plant proteins, animal proteins, microbial proteins, or mixtures thereof.

With respect to claims 5-6 and 60-61, Feldbrugge did not disclose or suggest the thermoplastic extrusion products of the underlying base claims and intervening claims and further comprising wheat proteins.

With respect to claims 13 and 68, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising at least about 50% by weight of whey protein.

With respect to claims 23-26 and 78-81, Feldbrugge did not disclose or suggest thermoplastic extrusion products wherein the whey protein comprised sweet whey solids, whey protein concentrate, whey protein isolate, or mixtures thereof.

With respect to claim 82, Feldbrugge did not disclose or suggest a thermoplastic extrusion product wherein the whey protein is undenatured.

With respect to claims 109-113 and 119, Feldbrugge did not disclose or suggest a thermoplastic extrusion product containing about 40-100% by weight of a whey protein concentrate and about 0-60% by weight of an edible polysaccharide, where the whey protein concentrate comprises at least about 80% by weight of protein. Still further, with respect to claim 110, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising about 40-99% by weight of whey protein concentrate and about 1-60% by weight of edible polysaccharide.

For these reasons, Feldbrugge failed to disclose each and every limitation of the presently claimed invention.

c. Feldbrugge Failed To Enable Making or Using of the Claimed Invention

Enclosed with this paper is the Declaration of Conly L. Hansen. This declaration was not presented earlier because the Feldbrugge patent does not disclose each and every element of the invention as claimed. Due to this defect in the alleged *prima*

facie case of obviousness, it was not thought necessary to provide additional evidence of the nonobviousness of the claimed invention. In view of the USPTO having maintained the rejection of claims despite a lack of a *prima facie* case of obviousness, Applicants now provide additional evidence of the failings of the Feldbrugge patent. Therefore, the submission of this declaration is timely and should be considered along with other evidence previously submitted and now submitted.

Dr. Hansen is an expert in the fields of food science and agricultural engineering due to his education, work experience on the faculties of Ohio State University and Utah State University for about 27 years combined, original research, teaching, and other professional attainments. His declaration gave his opinion that the disclosure of Feldbrugge patent was not sufficient to enable a person of ordinary skill in the relevant art to make and use the invention. He further opined that, due to the insufficiency of the disclosure in the Feldbrugge patent, it would not have been obvious to a person of ordinary skill in the art to bridge the gap between what is disclosed in Feldbrugge and what is claimed in the present application.

d. Feldbrugge Failed To Support a Prima Facie Case of Obviousness

In view of the above, Applicant respectfully submit that a *prima facie* case of obviousness has not been established for

failure to show each and every limitation of the presently claimed invention in the prior art and because Feldbrugge would not enable a person of ordinary skill in the art to make and use the presently claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

2. Claims Rejected over the Combination of the Feldbrugge and Villagran References

Claims 17, 18, 72, 73, 114, and 115 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldbrugge taken together with U.S. Patent No. 5,366,748 ("Villagran").

The Feldbrugge patent was summarized above. Villagran discloses a method of producing an extruded cereal-grain-based food product. In this process, the extruder is simply a mixer for forming a dough. There is no heating, and there is minimal shear in the extruder. The resulting sheet of dough is then cut into segments and fried (col. 1, lines 65-68). A gum may be added to the dough to prevent toothpacking.

The combination of Feldbrugge and Villagran fails to make up for the deficiencies of the Feldbrugge reference alone. That is, claims 17-18, 72-73, and 114-115 are dependent claims. As such, they incorporate by reference all of the limitations of their underlying base claims and intervening claims. The combination of Feldbrugge and Villagran fails to disclose each and every limitation incorporated by reference. Therefore, a *prima facie*

case of obviousness has not been established with respect to these claims. Therefore, withdrawal of the rejection is respectfully requested.

3. Claims Rejected over the Combination of the Feldbrugge and JP 58-282325 References

Claims 19-21, 74-76, and 116-118 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldbrugge taken together with JP 58-28235.

Feldbrugge has been described above. JP 58-282325 disclosed preparation of a food product by blending a milk-protein-containing hydrous gel with a dehydrating agent (such as sodium chloride, calcium chloride, calcium lactate, a monosaccharide, an oligosaccharide, a sugar alcohol, an amino acid or salt thereof, or lecithin) and a powdery dispersant (such as dextrin, cellulose powder, gum, white powder) under heating, followed by extruding and molding. The milk protein is from milk or defatted milk, or is casein. This is not the same as whey protein.

The combination of Feldbrugge and JP 58-28235 failed to make up for the deficiencies of the Feldbrugge reference alone. That is, claims 19-21, 74-76, and 116-118 are dependent claims. As such, they incorporate by reference all of the limitations of their underlying base claims and intervening claims. The combination of Feldbrugge and JP 58-28235 fails to disclose each and every limitation incorporated by reference. Therefore, a

prima facie case of obviousness has not been established with respect to these claims. Therefore, withdrawal of the rejection is respectfully requested.

4. Cited References Were Not Considered in Their Entireties

References must be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985).

Feldbrugge discloses a dense, fibrous product that simulates meat. Feldbrugge teaches mixing the ingredients in a mixer and then feeding the resulting dough through a simple heated extruder without the use of an exit die. There is substantial shear in the extrusion process. Therefore, when considered as a whole, Feldbrugge teaches away from mixing in the extruder and away from using an exit die, both of which teach away from the presently claimed invention, but suggests using heat and shear forces in the extrusion process.

Villagran discloses a method of producing an extruded cereal-grain-based food product. In this process, the extruder is simply a mixer for forming a dough. There is no heating, and there is minimal shear in the extruder. The resulting sheet of dough is then cut into segments and fried. Therefore, when

considered as a whole, Villagran teaches that the extruder is simply a mixer, that no heating is to take place in the extruder, and that the extruded product is to be fried.

JP 58-282325 discloses preparation of a food product by blending a protein-containing hydrous gel with a dehydrating agent and a powdery dispersant under heating, followed by extruding and molding.

When considered in their entireties, Feldbrugge and Villagran contradict each other. One reference teaches to mix the ingredients before placing them in the extruder, while the other reference teaches to mix the ingredients in the extruder. One reference teaches to heat the ingredients in the extruder, and the other references teaches not to heat in the extruder. One references teaches to exert substantial shear forces on the ingredients in the extruder, and the other reference teaches away from exerting substantial shear forces. Therefore, it is respectfully submitted that these two references, when considered in their entireties, teach away from each other. Hence, their combination is illegitimate for use as a basis for rejecting the instantly claimed invention.

Feldbrugge and JP 58-282325 both teach making meat-like products. The disclosure of JP 58-282325 is so brief and ambiguous that it is uncertain as to what it actually teaches. The ingredients are blended while being heated, then they are

extruded and molded. However, it is not certain as to whether the blending takes place in the extruder or in a mixer, whether the heating takes place in the extruder or elsewhere, whether or not substantial shear forces are exerted on the blend, whether or not an exit die is used on the extruder, and so forth. JP 58-282325 teaches using casein or proteins from milk, not whey proteins.

What is a person of ordinary skill in the art to learn from these disclosures? It is not certain, but it is clear that whatever these combinations of references teach, it is not the presently claimed invention. The Office Action has picked and chosen isolated teachings from the cited references without guidance in the prior art to do so. This violates accepted procedure for making a determination under Section 103. For this reason, a *prima facie* case of obviousness is lacking.

5. Hindsight Reconstruction of the Claimed Invention Using the Applicant's Description as a Blueprint Is Improper

The C.C.P.A. stated in In re Carroll, 202 U.S.P.Q. 571, 572 (C.C.P.A. 1979):

One of the more difficult aspects of resolving questions of non-obviousness is the necessity "to guard against slipping into use of hindsight." Graham v. John Deere Co., 383 U.S. 1, 36, 148 USPQ 459, 474 (1965). Many inventions may seem obvious to everyone after they have been made. However, 35 USC 103 instructs us to inquire into whether the claimed invention "would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains." Thus, in deciding the issue of obviousness, we must look at the prior art presented from a vantage point in time prior to when the invention was made, and through the eyes of a hypothetical person of ordinary skill in the art.

Moreover, it has been widely recognized that virtually every invention is a combination of elements and that most, if not all, of these will be found somewhere in an examination of the prior art. This reasoning led the Federal Circuit, in Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983) to state:

The test is whether the claimed invention as a whole, in light of all the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Still further, the Federal Circuit stated as follows:

Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 4225, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." *Id.* Here, the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination. But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest

that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore*, 721 F.2d at 1553, 220 USPQ at 312-13. It is essential that "the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

In re Fine, 837 F.2d 1071, 5 USPQ2d 1596, 1599-1600 (Fed. Cir. 1988).

These cases make it clear that if the PTO is to establish a prima facie case of obviousness, it is not sufficient to merely assert that "it would be obvious."

Applicant respectfully submits that if one follows the above guidelines and analyzes the art properly, then there is no suggestion of the invention as claimed. The Office Action has picked certain disclosures of the cited references, ignoring others, without guidance from the prior art to do so. This is exactly the type of hindsight reasoning that is forbidden by the law. For this reason, Applicants respectfully submit that a prima facie case of obviousness has not been established.

6. The Requirements of Graham v. John Deere Have Not Been Followed

Graham v. John Deere requires that the scope and content of the prior art be determined, the differences between the prior art and the claimed invention be set out, and the level of ordinary skill in the art be determined.

In the present instance, the scope and content of the prior art has been given short shrift, because the references were not considered in their entireties. The inconsistencies and contradictory teachings of the references were ignored. Isolated teachings were selected, while other teachings were likewise ignored. Similarly, the differences between the cited references and the claimed invention have been largely ignored or glossed over. Further, the level of skill in the art has not been established.

Therefore, it is respectfully submitted that proper procedure has not been followed. For this reason, a *prima facie* case of obviousness has not been established.

II. Conclusion

The preponderance of the evidence weighs in favor of the patentability of the presently claimed invention. The cited references, alone or in combination, fail to teach each and every limitation of the claimed invention. The cited references were not considered in their entireties. The cited references teach

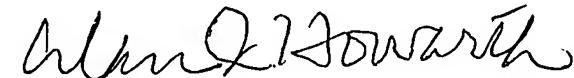
away from making the presently claimed invention and from being combined. Improper hindsight reconstruction of the invention was used.

Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicants respectfully request reconsideration and allowance of Claims 1-6, 13-26, 56-61, 68-82, and 109-119 and passage of this application to issue.

DATED this 25th day of May, 2007.

Respectfully submitted,



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